IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

PAUL SCHILF and CYNTHIA SCHILF, as special administrators for the ESTATE OF PETER RAYMOND SCHILF, Deceased, and PAUL SCHILF and CYNTHIA SCHILF, Individually, **Plaintiffs,** **vs.** **ELI LILLY AND COMPANY, et al.** **Defendants.**	**Case No. CIV. 4:2007CV04015-LLP**

DEFENDANTS' SUPPLEMENTAL MEMORANDUM IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' FAILURE TO WARN CLAIM AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON THE LEARNED INTERMEDIARY DOCTRINE

Defendants Eli Lilly and Company and Quintiles Transnational Corporation, respectfully submit this statement to address legal and factual issues raised during the September 20, 2010 Pretrial Conference and in the Court's September 22, 2010 Order.

A. Dr. Briggs' Testimony Is Sufficient Under the Majority Approach.

When addressing the issue of proximate cause in the context of a prescription drug case, the overwhelming majority of courts hold that unequivocal testimony from a prescribing physician is dispositive.[1] Indeed, on October 4, 2010, the United States Court of Appeals for the

[1] *See, e.g., In re Fosamax Prods. Liab. Lit.*, 2010 WL 1257299 at *3 (S.D.N.Y. March 26, 2010) ("[I]t is *the prescribing physician's* hypothetical course of conduct ... that is most relevant to the issue of proximate cause") (emphasis added); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 WL 483574, at *6 (E.D. La. Feb. 20, 2008) (granting summary judgment because "cases governed by the learned-intermediary doctrine often *turn on the testimony of the prescribing physician*"), *aff'd sub nom.* 314 Fed. Appx. 701 (5th Cir. 2009) (emphasis added); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 997-98 (C.D. Cal. 2001) ("*most cases* do not permit a plaintiff to get past summary judgment where the doctor made unequivocal statements in a pre-trial deposition demonstrating that

Second Circuit issued summary orders affirming grants of summary judgment in several cases based on the prescriber's testimony that a different warning would not have changed his or her prescribing decisions. *See* Summary Orders (attached as Exhibit A). The rationale for this approach is simple: the prescribing physician is the only witness who can testify about what he or she would have done in response to an adequate warning. "Objective" evidence about a "reasonable physician" has no impact on plaintiff's burden of establishing proximate causation. *See Stafford v. Wyeth*, 411 F. Supp. 2d 1318, 1322 (W.D. Okla. 2006) ("The question in the learned intermediary context is not what an objective physician would decide, but rather what plaintiff's doctor would determine"), citing *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478, 1485 (E.D. Okl. 1997)).[2] Under the majority approach,[3] Dr. Briggs' testimony is more than sufficient to entitle Defendants to summary judgment.[4]

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adequate warnings would not have affected his or her decision to prescribe a drug") (footnote and citations omitted) (emphasis added), *aff'd*, 358 F.3d 659 (9th Cir. 2004); *Ebel v. Eli Lilly and Co.*, No. 08-40170, 2009 WL 837325 (5th Cir. March 30, 2009); *Porter v. Eli Lilly and Company*, No. CIVA 106CV-1297, 2008 WL 544739 (N.D. Ga. 2008), *aff'd*, No. 08-11335, 2008 WL 4138115 (11th Cir. Sept. 9, 2008); *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003-04 (4th Cir. 1992); *Plummer v. Lederle Laboratories*, 819 F.2d 349, 358 (2d Cir. 1987); *Eschete v. Roy, et al.*, 554 F. Supp. 2d 628, 634-35 (E.D. La. 2008); *Fisher v. Bristol-Myers Squibb Co.*, 181 F.R.D. 365, 370 (N.D. Ill. 1998); *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 710 (E.D. Tex. 1997); *Windham v. Wyeth Laboratories, Inc.*, 786 F. Supp. 607, 612 (S.D. Miss. 1992); *Lineberger v. Wyeth*, 894 A.2d 141, 151 (Pa. Super. 2006). *Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 978-979 (N.D. Ind. 1999); *Parks v. Danek Med. Inc.*, No. 2:95CV206, 1999 WL 1129706 at *6 (N.D. Ind. June 17, 1999); *Madsen v. American Home Products Corp.* 477 F. Supp. 2d 1025, 1035 (E. D. Mo. 2007); *see also In re Zyprexa Products Liability Litigation*, 2009 WL 2487305 (Carey) (E.D.N.Y. July 27, 2009) (applying Virginia law and granting summary judgment on learned intermediary grounds because prescriber's testimony established that a different warning would not have changed the prescriber's conduct); *Dean v. Eli Lilly & Co.*, No. 07-CV-4505, 2009 WL 2004540 (E.D.N.Y. July 1, 2009) (applying Florida law) (same); *Washington v. Eli Lilly & Co.*, No. 06-CV-2592, 2009 WL 2163118 (E.D.N.Y. July 13, 2009) (applying Michigan law) (same); *Clark v. Eli Lilly & Co.*, No. 06-CV-1600, 2009 WL 1514427 (E.D.N.Y. May 29, 2009) (applying Pennsylvania law) (same); *Smith v. Eli Lilly & Co.*, 653 F.Supp.2d 181 (E.D.N.Y.2009) (applying Arkansas law) (same); *Pruett v. Eli Lilly & Co.*, No. 07-CV-1931, 2009 WL 2245068 (E.D.N.Y. July 22, 2009) (applying Alabama law) (same); *Quirarte v. Eli Lilly & Co.*, No. 07-CV-1161, 2009 WL 3597194 (E.D.N.Y. Oct. 16, 2009) (applying Illinois law) (same); *Treuchel v. Eli Lilly & Co.*, No. 08-CV-01176, 2009 WL 5216930 (E.D.N.Y. Dec.21, 2009) (applying Minnesota law) (same).

[2] The Court cited to *Stafford* at the Pretrial Conference and stated that it had "grave doubts" about plaintiffs' failure to warn claim. *See also Gronniger v. American Home Products Corp.*, No. 3584, 2005 WL 3766685 at *5 (Pa. Com. Pl. Oct. 21, 2005) (rejecting "reasonable doctor" affidavit). Defendants respectfully submit that South Dakota would follow this majority rule. *See Gilbert v. Flandreau Santee Sioux Tribe*, 2006 SD 109, ¶ 22, 725 N.W.2d 249,

B. Dr. Briggs' Testimony Is Sufficient Under the Minority Approach Expressed in *Thomas v. Hoffman-LaRoche, Inc.*

Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 812 (5th Cir.1992) never suggests that clear, unequivocal testimony from a prescribing physician may not be dispositive on this issue. *Thomas* holds that a plaintiff (or defendant) may rely on the prescriber's testimony and explains that the proximate cause inquiry focuses on whether a different warning would have influenced the prescriber. *Id.* "Reasonable physician" evidence is relevant only to the extent it casts light on what the prescriber would have done. *Id.*

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256 (the South Dakota Supreme Court looks to the law of other states); *Murray v. Mansheim*, 2010 SD 18, ¶ 15, 779 N.W. 379, 386 ("We necessarily turn our focus to other authorities for guidance.").

[3] Rather than address the majority approach, Plaintiffs' Response to the Court's Order of 9/22/10 ("Plaintiffs' Response") cites a number of Oklahoma cases (some of which do not even address the learned intermediary doctrine) that discuss the heeding presumption, and states that the heeding presumption applies in South Dakota. There is no authority indicating that the South Dakota Supreme Court has adopted the heeding presumption in cases involving the learned intermediary doctrine. While Plaintiffs cite to *McElhaney v. Eli Lilly and Co.*, 739 F.2d 340 (8th Cir. 1984), that case only cites to comment *j* for the proposition that a seller "is required to give a warning 'if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge' of the danger." (*quoting* Restatement § 402A, cmt. *j*). The opinion does not mention a heeding presumption and does not predict that the South Dakota Supreme Court would actually adopt comment *j*. Furthermore, some courts that recognize a heeding presumption have held that it does not apply in the context of a pharmaceutical case involving a learned intermediary doctrine because the policies justifying the presumption that an individual will read and heed a product's warning are not served in learned intermediary cases. *See Koenig v. Purdue Pharma. Co.*, 435 F. Supp. 2d 551, 556-57 (N.D. Tex. 2006) (holding that the read and heed presumption could not apply in a learned intermediary case). The purposes of the heeding presumption are (1) to excuse plaintiffs from having to make self-serving assertions that they would have followed adequate instructions, and (2) to assist plaintiffs in cases where the person to whom the warnings are directed has died, and evidence of what he would have done is unavailable for that reason. *Id.* at 557 (*citing General Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex. 1993). In learned intermediary cases, physicians, rather than plaintiffs, provide testimony about the decision to prescribe the product at issue. Thus, there is no need to assume the doctor would "heed" the warning – he can testify about whether he would or would not. As a result, neither of the factors supporting the read and heed presumption are applicable. *Koenig*, 435 F. Supp. 2d at 557; *see also Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 814 (5th Cir. 1992). Furthermore, Plaintiffs' statements to the contrary, where courts apply the heeding presumption in learned intermediary doctrine cases, they usually hold that it is rebutted by evidence about the prescriber as opposed to a "reasonable physician." *See, e.g.*, *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir. 2003) ("the defendant can rebut the presumption through testimony that a different warning would not have made a difference in the actions of the physician."); *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1021 (10th Cir. 2001) ("We hold that defendants provided sufficient evidence that Dr. Rogers would have not changed her course of treatment.").

[4] Dr. Briggs' testimony is more than sufficient because it is Plaintiffs' burden to come forth with evidence of proximate cause, not Defendants' burden to disprove proximate cause. Indeed, if there were no testimony whatsoever on this issue, Defendants would be entitled to summary judgment because Plaintiffs have the burden of proof and have offered no evidence on an essential element of their claims.

In *Thomas* the plaintiff's expert testified that a reasonable physician would not have prescribed the drug for the plaintiff, and the prescriber testified that a revised warning would not have changed his decision. *Id.* at 811. The Fifth Circuit resolved this conflict in favor of the prescriber's testimony. *Id.* at 818. While the Fifth Circuit did not focus solely on the prescriber's testimony, *Thomas* is best read as consistent with the majority approach.[5] Under *Thomas*, Dr. Briggs' unequivocal testimony is sufficient to entitle Defendants to summary judgment.

C. Dr. Briggs' Testimony Is Sufficient Under the Minority Approach Expressed in *In re Prempro Products Liability Litigation*.

In re Prempro Products Liability Litigation, 2006 WL 1981902 (E.D. Ark. 2006) also does not preclude a grant of summary judgment to Defendants. It holds that a plaintiff cannot establish proximate cause "if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." *Id.* at *2. Dr. Briggs' testimony demonstrates that he had independent knowledge about information contained in the eventual black box warning. He was aware of the FDA's October 15, 2004 Public Health Advisory. Doc. No. 124. His testimony on this point is unequivocal and undisputed, and Plaintiffs concede as much. Doc. No. 143, p. 8. He discussed this advisory and its content with Plaintiff Cynthia Schilf and Decedent. Doc. No. 156, pp. 17-18. Thus, *Prempro* supports granting summary judgment to Defendants because Dr. Briggs' knowledge of Cymbalta® was substantially the same as that which was contained in the eventual black box warning.[6]

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[5] In *Motus v. Pfizer*, the court cited specifically to *Thomas* and interpreted the Fifth Circuit's opinion in that case as supporting the majority view that summary judgment dismissal is warranted if the prescriber offers unequivocal and undisputed testimony that different warnings would not have altered the prescription. 196 F. Supp. 2d 984, 997-98 (C.D. Cal. 2001).

[6] Also, the *Prempro* court noted that a prescriber's testimony might raise credibility issues unless the testimony is "self-disserving." *Id.* at *3. To the extent the *Prempro* court took this position, it is squarely within the minority of courts. As the court in *Motus v. Pfizer* explained, the majority of courts "do not permit a plaintiff to get past

D. Dr. Glenmullen's Affidavit Does Not Create A Material Issue Of Fact.

Even were the Court to hold that South Dakota would adopt the minority approach, Dr. Glenmullen's affidavit is not sufficient to create a material issue of fact. Dr. Glenmullen's affidavit cannot create a material issue of fact because he admittedly is not an expert in drug warnings and labeling, and because Dr. Glenmullen's affidavit is internally inconsistent, contradicts his prior sworn testimony in this case, and ignores the factual record.

1. Dr. Glenmullen is Admittedly Not An Expert on Drug Labeling or Warnings.

Dr. Glenmullen's affidavit testimony on how a reasonable physician would have acted had they received a different warning is not reliable in light of his prior testimony under oath that he is not an expert on drug labeling and warnings issues. *See* Jan. 27, 2005 Deposition of Dr. Joseph Glenmullen, taken in *In Re Paxil Prod. Liab. Litig.*, No. CV-01-7937 MRP, CWx (C.D. Cal 2005) at 55:13-20 ("Q: Do you hold yourself out to be an expert in drug labeling and warning issues? A: No. Q: Have you ever advised a drug manufacturer on warnings or labeling for a prescription drug? A: No.") (attached as Exhibit B). Furthermore, despite submitting two separate expert reports in this case, Dr. Glenmullen has never offered any opinions with respect to what a "reasonable prescriber" would have done in response to the 2005 pediatric black box warning.

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summary judgment where the doctor made unequivocal statements in a pre-trial deposition demonstrating that adequate warnings would not have affected his or her decision to prescribe a drug." 196 F. Supp. 2d 984, 997-98 (C.D. Cal. 2001) (collecting cases on both sides and deciding to join the courts embracing the majority approach); *see also Woulfe*, 965 F. Supp. at 1485 (rejecting plaintiff's argument that prescriber's testimony inherently raises credibility issues as "implausible reasoning"). In any event, Plaintiffs have not identified any evidence that undermines Dr. Briggs' credibility and there is no reason to believe that Dr. Briggs' testimony was self-serving. As he was a co-defendant at the time of his deposition, he arguably could have improved his position in the case by attempting to shift blame to Lilly.

2. Dr. Glenmullen's Affidavit Cannot Create A Material Issue of Fact.

Dr. Glenmullen's affidavit is unreliable, and cannot create a material issue of fact, because it is internally inconsistent, contradicts his prior sworn testimony, and ignores the factual record. Dr. Glenmullen's affidavit is internally inconsistent because it both suggests that a reasonable prescriber would not have prescribed Cymbalta® and suggests that a reasonable prescriber may have prescribed Cymbalta®, but would have given a more specific warning when doing so. *Compare* Glenmullen Affidavit ¶ 2 and ¶ 3.

It is also inconsistent because it suggests that a reasonable physician with knowledge of the information disclosed in the coming black box warning would not have prescribed Cymbalta®, but would have prescribed another antidepressant. However, this ignores that the black box warning was a class-wide warning that was imposed on all antidepressants. Thus Dr. Glenmullen's suggestion that the black box warning would have caused a reasonable prescriber to choose Prozac® or another antidepressant over Cymbalta® makes no sense when each of these medications was going to carry the exact same warning disclosing an identical potential risk. By suggesting that a reasonable prescriber would have selected a treatment that carried the same warning language as Cymbalta®, Dr. Glenmullen necessarily suggests that a reasonable prescriber would prescribe Cymbalta®.

Dr. Glenmullen's affidavit is also unreliable because it conflicts with his prior sworn testimony in this case. In his affidavit, Dr, Glenmullen testified that a reasonable physician would not have prescribed Cymbalta® to Decedent. However, Dr. Glenmullen testified at his deposition that he continues to prescribe antidepressants (despite the fact that the black box warning at issue in this case is on the labels of all SSRI and SNRI antidepressants). *See* Doc No. 116-4 (July 30, 2008, Glenmullen Dep.) 147:9-18. Dr. Glenmullen also testified that he has prescribed Cymbalta® since the implementation of the pediatric and adolescent black box

warning. *See* Doc No. 116-4 at 53:6-54:8. In light of his own prescribing conduct, Dr. Glenmullen cannot credibly state that a reasonable prescriber would not have prescribed Cymbalta® or other antidepressants following the implementation of the black box warning, as any such testimony is directly undercut by his own actions.

His affidavit also contradicts the deposition testimony cited on page 3 of Plaintiffs' Response. In the deposition testimony, Dr. Glenmullen states that physicians misinterpret over-stimulating side effects as improvement, while in the affidavit he makes the opposite claim that doctors misdiagnose those side effects as a failure to respond and therefore increase the dose of antidepressants. These statements directly contradict one another and also ignore the undisputed facts that Dr. Briggs believed Decedent was improving based both on his observations, and Decedent's subjective reports.

In addition, Dr. Glenmullen's affidavit ignores the factual record developed during the depositions of Dr. Briggs and Plaintiffs. In paragraph 2 of the affidavit, Dr. Glenmullen refers to a number of so-called "given facts," but these facts all relate to information that Dr. Briggs was aware of and/or that were disclosed in the package insert that Dr. Briggs had read. There is no dispute that Dr. Briggs knew of the impending black box warning, knew about the studies upon which the black box warning was based, knew what a black box warning means, knew that Cymbalta® was an SNRI drug, knew that he was prescribing Cymbalta® off-label because it was not approved for pediatric patients, and advised Cynthia Schilf and Decedent about the studies the FDA analyzed when deciding to implement the black box warning. The Cymbalta® package insert clearly disclosed that there had been suicides and attempted suicides during the Cymbalta® clinical trials. In paragraph 3 of the affidavit, Dr. Glenmullen claims that an objectively reasonable physician would have alerted Decedent and his parents about "side effects

that are potential precursors or warning signs" of suicidality. Those "potential precursors" are listed in the Cymbalta® package insert as well as instructions that families and care-givers should be alerted to monitor patients for such symptoms and to report such symptoms to the physician immediately.

All of the information that Dr. Glenmullen suggests would have caused a "reasonable doctor" to act differently was information that Dr. Briggs was in fact aware of and had at his disposal.[7] To the extent that Dr. Glenmullen believes that "doctors being warned so they can warn patients is the essential element in keeping patients safe on the drugs" (Glenmullen Affidavit at ¶ 3), the evidence establishes that Dr. Briggs had the information that was present in the black box warning.

Finally, as Dr. Glenmullen's affidavit leaves open the possibility that a reasonable prescriber would have prescribed Cymbalta® to Decedent, it cannot create a material issue of fact sufficient to defeat summary judgment. Indeed, even the cases cited in the Court's Sept. 22, 2010 Order recognize that, in order to create a fact question with respect to causation, a plaintiff must show that an adequate warning "would have convinced the treating physician not to prescribe the product for the plaintiff." *See Thomas,* 949 F.2d 8 at 812; *In re Prempro Products,* 2006 WL at *2. Even under these more lenient requirements, Dr. Glenmullen's affidavit is not sufficient to create a fact question that avoids granting summary judgment to

[7] Indeed, Plaintiffs have conceded in pleadings to this court that Dr. Briggs was aware of the coming black box warning and warnings contained therein. See Doc. No. 143 at n.8. (It "is clear that Dr. Briggs made some effort to stay current on the issue [of antidepressant black box warnings]. He was clearly aware of it."). Dr. Briggs' independent knowledge is confirmed by the deposition testimony of Paul and Cynthia Schilf. Cynthia Schilf testified in her deposition that Dr. Briggs told her that some people believe that antidepressants are associated with suicide. Depo of Cynthia Schilf at 155:4-14 (Attached as Exhibit C). Furthermore, Paul Schilf testified that Dr. Briggs advised Cynthia Schilf about restlessness, stating that Cynthia had told him that there could be restlessness and sleeplessness from Cymbalta® and that Dr. Briggs had prescribed Sonata in part to help alleviate any potential restlessness and sleeplessness. Depo of Paul Schilf at 146:1-9 (Attached as Exhibit D).

Defendants. His litigation-driven testimony on what a "reasonable prescriber" would do cannot trump the undisputed and unequivocal testimony of the *actual* prescriber on this issue.

II. CONCLUSION

In light of the foregoing, the Court should enter an order granting Defendants' Motion for Summary Judgment on Plaintiffs' Failure to Warn Claim and denying Plaintiffs' Motion for Summary Judgmcnt on the Learned Intermediary Doctrine.

Dated this 4th day of October, 2010.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this, the 4th day of October, 2010, I electronically filed the foregoing Defendants' Supplemental Memorandum in Support of Their Motion for Summary Judgment on Plaintiffs' Failure to Warn Claims and In Opposition to Plaintiffs' Motion for Summary Judgment on the Learned Intermediary Doctrine with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to the following parties:

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